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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE	*Application Number*	09/934,114
	Filing Date	22 August 2001
	First Named Inventor	Roland K. McGREADY
	Group Art Unit	1648
	Examiner Name	S.A. Foley
	Attorney Docket No.	2344-103

Title of the Invention: **ANTI-PARATOPIC ANTIBODY AS AN IMMUNOGEN**

RESPONSE TO RESTRICTION REQUIREMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

In response to the Restriction Requirement mailed 18 December 2002, Applicant hereby provisionally elects Group I, claims 17-24 and 28-30 with traverse.

The Examiner alleges that the invention of Group I is distinct from the inventions of Groups II and III because the method of Group I can be used to make different antibodies. However, this allegation is in error. The method of Group I is directed to producing anti-paratopic antibodies. The anti-paratopic antibodies are antibodies which bind antigens of an aetiological agent. One example, i.e., species, of an aetiological agent is HIV. The fact that different anti-paratopic antibodies can be produced for different species of aetiological agents, does not indicate that the method used to produce such anti-paratopic antibodies is patentably distinct from the product produced by the method as required for restriction. Even though the specificity of the anti-paratopic antibodies may be different, they are nevertheless all anti-paratopic antibodies. Thus, the method of Group I can only be used to produce anti-paratopic antibodies. Therefore, restriction between Groups I, II and III is improper.

In addition, the anti-paratopic antibodies of Groups II and III are made by the method of Group I, as required by the claims. The anti-paratopic antibodies cannot be made by any other method. Since the anti-paratopic antibodies cannot be made by any other method, restriction between Groups I, II and III is thus improper.

Furthermore, there are two criteria for a proper requirement for restriction between patentably distinct inventions: 1) The inventions must be independent or distinct as claimed; and 2) There must be a serious burden on the Examiner if restriction is not required. See MPEP § 803. Examiners must provide reasons and/or examples to support conclusions. For purposes of the initial requirement, a serious burden on the Examiner may be *prima facie* shown if the Examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP § 808.02. That *prima facie* showing may be rebutted by appropriate showings or evidence by the applicant. Insofar as the criteria for restriction practice relating to Markush-type claims is concerned, the criteria are set forth in MPEP § 803.02. See MPEP § 803. If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the Examiner must examine all claims on the merits, even though they are directed to independent and distinct inventions. In such a case, the Examiner will not require restriction. See MPEP § 803.02.

Concerning the claims of the present application, claims 17-24 and 28-30 are drawn to a method of producing anti-paratopic antibodies and claims 25-27 are directed to anti-paratopic antibodies produced by this method. Although anti-paratopic antibodies to individual aetiological agents may be distinct from each other, this distinctness alone is not enough to require a restriction, as stated in the MPEP and as discussed above. There must also be a serious burden upon the examiner. In the absence of such a burden, the examiner must examine all of the claims. It is urged that the burden of examining all of the claims of the present application is not a serious one, and that the burden of examining all of the claims is only slightly greater than examining one of the groups of claims.

The examination entails various aspects. First is a decision concerning utility under 35 U.S.C. §101. It is submitted that a decision concerning utility will be identical for a method of producing anti-paratopic antibodies and the anti-paratopic antibodies produced by the method. Thus, there is no added burden of examining all of the Groups as compared to examining only a single Group.

The second aspect of examination is whether the provisions of the various paragraphs of 35 U.S.C. § 112 have been met. In general, and in this case, this means reviewing the application and

Consequently, it is submitted that the only reason for restriction is that one species of anti-paratopic antibody may be distinct from a second species of anti-paratopic antibody, although the method to produce each is identical with the exception of the aetiological agent. But as explicitly stated in MPEP § 803, the inventions must be distinct and there must be a serious burden on the examiner. MPEP § 803.02 states that if a search and examination of an entire claim can be made without serious burden, the examiner must examine all claims on the merits, even though they are directed to independent and distinct inventions. As urged above, it is asserted that examination of all of the Groups will not impose a serious burden.

In view of the above arguments, it is requested that the restriction requirement imposed in the Office Action mailed 18 December 2002 be reconsidered and that all of claims 17-30 be examined together.

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